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ALLOPOLYHERBO TABLET FORMULATION AND EVALUATION FOR MIGRAINES FROM DIRECT COMPRESSION METHOD

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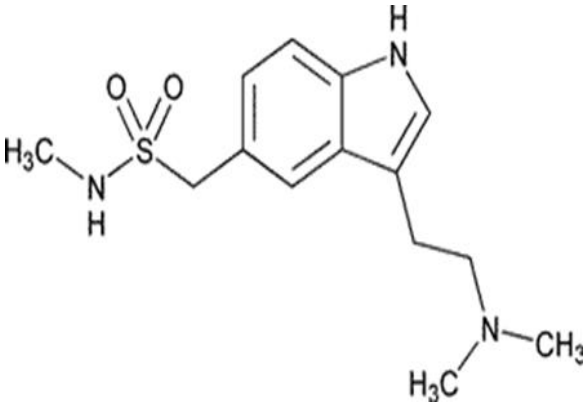
ABSTRACT

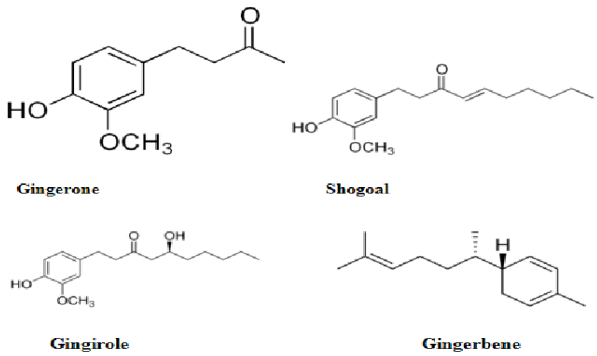
The formulation research towards the safety and reduce the side effects of a containing Sumatriptan succinate, ginger and black pepper were prepared by direct compression method. Both Sumatriptan succinate and ginger used as an anti-migraine agent. Ginger prevent the side effects of Sumatriptan as well as it act as binding and disintegrating agent into tablet formulation. Black pepper improve the bioavailability and shows the bio enhancing property of Sumatriptan succinate in the formulation. The Allopolyherbo tablet evaluating by various tests weight variation, friability, hardness as per standards and also perform the disintegration test, and dissolution studies. This study results that the allopolyherbo tablet is better results than conventional tablet.

INTRODUCTION

The triptan class of the drugs mainly prescribed into the treatment of migraine such Sumatriptan succinate (SUM). Its IUPAC name is 3-[2-(Dimethylamino) ethyl] –N-methyl-1H indole -5-methane sulphonamide succinate. SUM shows the agonistic activity on 5HT1D and 5-hydroxy tryptamine receptors and its subtypes. The SUM undergoes the biotransformation through the monoanino oxidase-A. It is used in the treatment of acute migraine relief or its attacks. Zingiber officinale i.e. Ginger belongs to family-Zingiberaceae. Ginger find in many of regions of India widely use in spice in many of countries condiment to add flavor to food. Ginger consisting two of categories herbal medicines of substances such as volatile and non-volatile constituents mainly in its rhizomes. Active ingredients is sesquiterpene, mono-terpenoid hydrocarbons also gingerols, shogaols, paradols, and zingerone. Its shows the good anti-inflammatory result.

Fig.1 Structure of Sumatriptan succinate, Gingerone, Gingirole, Shogoal, Gingerbene.





METHOD AND PREPARATION

1. Preparation of extract of ginger powder-

It below 45^{0}C extracted with the ethyl ether organic solvent distillate the mixture at reduce pressure to prevent decomposition of active ingredients. This concentrated ethanolic extract added poly vinyl pyrrolidine (PVP) stirred well. From the PCT application WO99/32130 improve the valuable ingredients of dry powders extracts of medicinal plants by the pyro vinyl pyrrolidones. Finally the paste vacuume dried then added into the formulation.

2. Preparation of guava leaves extract

The guava dried leaves 20g were extracted with 400 ml of 55% ethanol (v/v) at 47C for the 4.9 hours and extracted solution filtered and evaporated then freeze dried for several time obtain the powder of guava leaves which mainly shows anti-inflammatory activity by these extract.

3. Preparation of the Black pepper powder

Black pepper also known as kaali mirchi powder (Hindi). Making it is very easy, just simply sun dry whole peppers for one day and grind it into a smooth and fine powder.

4. preparation of ajowan extract

The soaking 500 g seeds of Carum copticum in 750 ml of 95% ethanol for 15 days. The clear extract obtained after filtration was concentrated in a water bath maintained at 55^0C to obtain a semisolid mass (weight 29.45 g). The extracted semisolid mass is dried at room temperature.

Table no.1 formulation of allopolyherbo tablet

Sr. no.	Ingredients use	Quantity	Uses
1.	Sumatriptan succinate	25gm	Anti-migraine
2.	Ginger powder	20gm	Bio enhancer
3.	Black pepper powder	12gm	Disintegrant
4.	Ajowan powder	6gm	Pain reliever
6.	Guava leaves extract powder	14gm	Anti-inflammatory
7.	Magnesium stearate	6gm	Lubricant
9	Pyro vinyl pyrrolidine	4gm	Bulk enhancer & Disintegrant

Preparation of tablets by direct compression method

The direct compression method conventionally use for the manufacturing of tables. Weigh all ingredients as per requirement Sumatriptan succinate 24gm, ginger powder, black pepper powder and guava leaves extract powder. Pass the all powders through the sieve no-80#. Transferred the powders into mortal-pestle for geometric mixing of powders then add magnesium stearate. PVP prevent the dehydration of gingerol. After sieving the uniform size particles are obtained. Powders were evaluated their flow properties such as bulk density, tapped density, and Carr's index. The tablets weight adjust 200mg at 8 station tablet punch machine carefully and punch the tablets.

EVALUATION OF TABLET

1. Hardness of tablets

Select the 5 tablets randomly from the batch of manufacture tested on hardness tester Monsanto hardness tester. Which is in kg/cm^3.

2. Weight uniformity test

From the batch select the 20 tablets randomly and weigh individually using electrical sensitive precision balance. The mean of 20 tablets were calculated and coefficient of variation each batch calculated.

3. Friability test

10 tablet were selected from each batch and by using the Roche friabilator this test is carried out. Select the parameter on Roche friabilator for 4min at 25 revolution per minutes then stopped. The dusted tablets reweight and calculate percent loses of tablets.

4. Disintegration time

The disintegration medium setup as per Indian Pharmacopoeial standards buffer solution of 900ml pH 7.8 maintain temperature between $350\text{-}39^0$ over the test. Six tablets selected randomly from each batch placed in cylindrical tube of basket but no disk was used. The time

note down at which tablet breaks into the small particles.

5. **Calibration curve for Sumatriptan succinate and ginger powder**

Prepare the the stock solution 10mg drug into the 10ml of distilled water ita becomes 1000ppm solution again withdraw from 10ml of stock solution 1ml of drug solution dilute with 10ml of distilled water its become the 100 ppm solution. Various dilution were prepared 0.01, 0.02, 0.03, 0.04, 0.06, 0.08 and 0.10, 0.12 microgram per ml with buffer pH 7.8.

Take the absorbance of this dilutions at 249nm by using UVVIS spectrophotometer. Plot the graph absorbance against concentration (mg %).

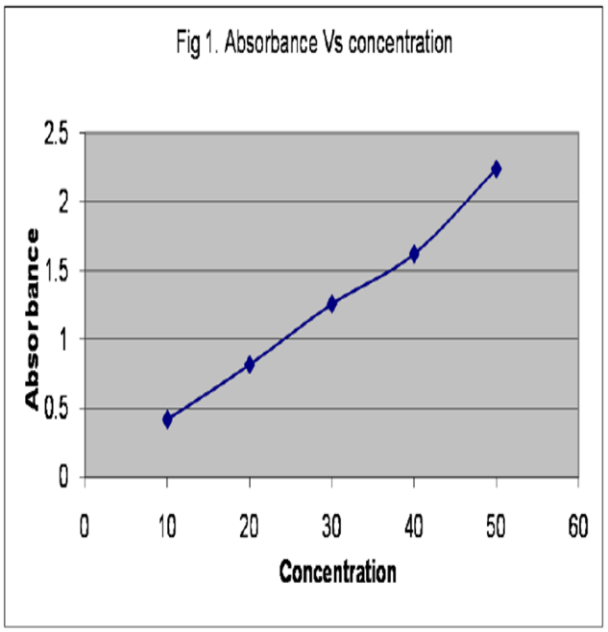


Fig.2 Calibration curve of Allopolyherbo tablet absorbance V/S concentration.

6. **Dissolution test**

Using the 900ml of phosphate buffer pH 7.8 as the medium rotating paddle at 50 rpm for 30 min. Withdraw the sample filter through the membrane filter disc of NMT 0.1 mm diameter. Reject first few ml of filtrate and dilute with same solvent with suitable volume. Measure the absorbance of the solution at the 249nm by using UV-VIS spectrophotometer.

7. **Stability studies**

Allopolyherbo tablet made by using plant extract powders kept at the room temperature 27^0C OR in refrigerator at 8^0C for the 4 weeks.

RESULT AND DISCUSSION

Allopolyherbo tablets were prepared, evaluated it's contain the Sumatriptan succinate and ginger powder as active ingredients. The ginger shows the reducing the side effects of Sumatriptan succinate and Bio-enhancer effectively. Powders hows the better flow properties and compressibility by using the PVP 12-15% concentration. Powder properties as following results.

Table no-2 powder flow properties

Powder Evaluation	Observations
Volume (cm3)	20 gram
Bulk density (g/cm3)	2.2 gram. /ml
Tapped density (g/cm3)	1.8 gram/ml
Angle of repose (o)	30.24^0
Carr's index	0.818

The powders shows the poor results of formulation low bulk density larger particles created void space consolidation of particles occurs. Disintegration within time limit at 3min. Disintegration study shows formulation have proper disintegration time. This could be due to appropriate quantity of binder used for these formulation.

Table no 3 - Evaluation parameters of Tablet

Tablet Evaluation	Observation
HARDNESS	35 kg/cm^3
Friability	0.30
Disintegration Time	3 min

The ginger powder formulation shows the below 1.0% friability and weight variation formulation acceptance the limit. Dissolution test shows the release of Sumatriptan succinate and ginger well within specified time. Graph of concentration vs. absorbance shows rate of release of Sumatriptan succinate and ginger in specified time limit. Shows calibration curve for standard Sumatriptan succinate. Percentage content of Sumatriptan succinate tablet by dissolution test occur 90.72 %. This shows ginger powder formulation where ginger does not hinder the release of Sumatriptan succinate. The graph Stability studies show that drug content did not change within first 14 days and even after 3 months. Tablets made of ginger extracts were more stable.

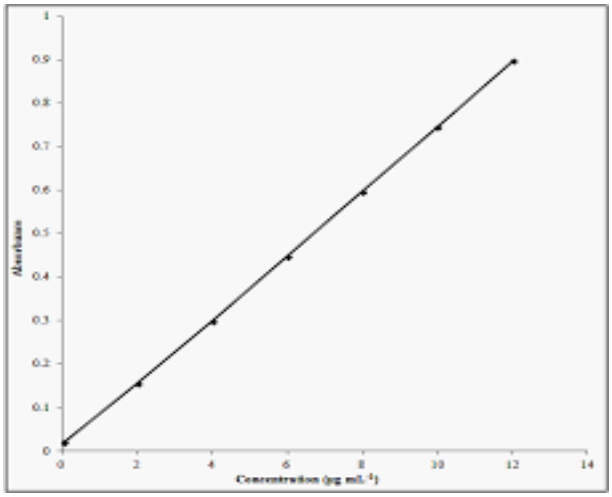


Fig. 3 Stability study of Allopolyherbo tablet

CONCLUSION

Ginger powder can be used instead of ginger extract with additional benefits. Ginger powder shows better compressibility as well as rapid disintegration thus allowing Sumatriptan succinate l to release faster.

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